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14. ABSTRACT

This award provides core program support to develop key capabilities of the Medical Device "Plug-and-Play" (MD PnP) Interoperability Program to lead medical device interoperability to support clinical solutions for improving patient safety and healthcare efficiency. Under MD PnP program leadership during 2014-2015, we have played a leadership role working on interoperability standards with ASTM, AAMI, ISO, and the AAMI/UL2800 Joint Committee developing standards for certifiable safety of medical device interfaces, and have developed core content for an ICE Data Logger draft standard to be submitted to a standards organization. We organized and disseminated clinical and system requirements that will facilitate adoption by device manufacturers, thereby providing products for procurement by the DoD and others. We led the submission to the FDA of a supplement to the pre-IDE for interoperable medical devices (published on our web site), and subsequent responses to FDA requests. We led a multi-institutional 20-day project in response to a government request for med-technology solutions to address the Ebola threat and inform SmartAmerica Global Cities Teams Challenge. In summary, we have leveraged our collaborative work with federal agencies, academia, industry, and standards development organizations to provide leadership, SME, and technical content to advance interoperability.

15. SUBJECT TERMS
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Introduction

A May 2004 symposium jointly sponsored by TATRC and CIMIT kicked off what became the Medical Device "Plug-and-Play" (MD PnP) interoperability program. Initially focused on creating a standardization framework for interoperability of medical devices in the Operating Room of the Future (ORF), the program collected clinical requirements from anesthesiologists, surgeons, and clinical engineers, and began to define an agenda for standards development. Within a year, we acknowledged that the need for interoperability encompasses the full continuum of healthcare environments not limited to the OR, and we developed a strategy to accelerate the development of interoperability technologies, as well as standards. This strategy addressed the need for a "sandbox" laboratory environment to facilitate the testing of devices and technologies with proposed standards; the development of a "plug-and-play" system architecture; collaboration with regulatory agencies; leveraging standards and technology to address vendors' liability concerns; and assuring the clinical relevance of all proposed interoperability solutions.

TATRC support, through a prior BAA and conference grants, has enabled the MD PnP interoperability program to develop key capabilities, to identify, access, and share numerous available resources, and to build collaborations to achieve MD PnP-identified objectives. TATRC's commitment has enabled us to attract additional program funding from Partners Information Systems, CIMIT, NSF, NIST, and NIH. We have created a $1M medical device interoperability laboratory in Cambridge, MA as a multi-institutional, interdisciplinary shared resource. We have developed clinical use cases demonstrating the capability of medical device interoperability to improve patient safety, and have exhibited these demonstrations at national meetings and held demonstrations for international audiences in our MD PnP Lab. In 2007, we held our first international conference on "Improving Patient Safety through Medical Device Interoperability and High Confidence Software", jointly sponsored by TATRC and NSF.

Significantly, core program support from TATRC enabled us to lead the writing of the first medical device integration system safety standard – the Integrated Clinical Environment (ICE) standard, ASTM F2761—Part 1, which includes functional architecture and risk mitigation strategies for networked, patient-centric interoperable medical devices. In addition, we led a successful collaborative effort involving four major healthcare delivery organizations to develop and adopt sharable interoperability contracting language for use in the procurement of medical devices and related equipment. We facilitated the endorsement of medical device interoperability for improving patient safety by fourteen medical societies (including the American Medical Association). We additionally worked with three companies on DoD SBIR projects to develop a first-responder ICE Supervisor. TATRC BAA support has been instrumental in providing "program glue" to effectively leverage these highly interdependent and synergistic activities to realize program objectives.

With the FDA and Continua Health Alliance, MD PnP through CIMIT planned and co-sponsored a three-day workshop on Medical Device Interoperability in January 2010. The workshop was attended by over 200 participants from industry, health care, and federal agencies. There has since been a follow-on working group, which meets regularly under MD PnP leadership, to address safety and regulatory concerns for integrated medical device systems. The FDA organized another meeting on device interoperability with AAMI in 2011, and, in 2012-2013, the

FDA had a Medical Device Interoperability Coordinating Council bring together various groups working on different aspects of interoperability. MD PnP played a leadership role in this activity.

Body of Report

The MD PnP Program has become a recognized leader in demonstrating clinical solutions for improving patient safety and healthcare efficiency through medical device interoperability. Interoperability will enable the creation of complete electronic health records and will introduce advanced capabilities, such as clinical error resistance, into networked medical device systems. We are producing a standardization framework consisting of a functional architecture and requirements for implementing standards in a manner that will support safe interoperability for effective clinical deployment. This requires critical evaluation (or "gap analysis") of potentially suitable candidate standards, as well as the modification of existing standards and the development of new standards for implementation in an MD PnP "standardization framework." By leveraging available standards, we expect to accelerate the MD PnP standards framework development so that useful candidate standards can be vetted and demonstrated. This includes partnering with industry and the FDA to define interoperability-related hazards and mitigation thereof to help inform regulatory science for networked medical device systems. This has also involved developing the MD PnP Laboratory as a "sandbox" populated with medical devices and test equipment to serve as a vendor-neutral environment to evaluate proposed standards and technologies. Building on our accomplishments to date, we have sought to leverage areas of traction around five key themes identified for this work:

- Standards Development
- Clinical and Engineering Requirements for Safe Medical Device Interoperability
- Interoperability & Security Requirements for Medical Device Procurement
- Regulatory Science for Safe Medical Device Interoperability
- Management of External Collaborations

Since the program's inception, more than 900 clinical and engineering experts, as well as representatives of more than 120 industrial and academic institutions have participated in our plenary workshops / conferences, working group meetings, lab demonstrations, and focus groups to contribute to ongoing program activities that helped shape the common goals. Our geographically dispersed, interdisciplinary, multi-institutional team of collaborators has included participants from: Kaiser Permanente, Johns Hopkins Medicine, Geisinger Health System, Vanderbilt, the VA, FDA, NIST, TATRC, computer and information science groups at University of Pennsylvania, University of Illinois at Urbana-Champaign, Kansas State University, University of New Hampshire, Waterloo University (Canada), Wiener Neustadt (Austria), Draeger Medical Systems, Philips Healthcare, GE Healthcare, Hospira, Intel, DocBox Inc., Moberg Research Inc., Linea Research Inc., Anakena Solutions Inc., LiveData Inc., MITRE Corporation, Lockheed Martin Corporation, IXXAT, Draper Laboratory, NSF/CPS (Cyber Physical Systems), and the Partners HealthCare System community (MGH Anesthesia, Biomedical Engineering at MGH and Brigham & Women's Hospital, and Partners HealthCare Information Systems).

Option-Year 2 activities have built upon all of our MD PnP program work to date and reflect our vision of progressing ICE (i.e. platform-based) medical device interoperability standards, continuing to develop and make available the clinical requirements for safe medical device interoperability, helping healthcare delivery organizations in general and the DoD in particular with strategies for the procurement of interoperable medical devices, working with the FDA to develop the regulatory science related to integrated medical device systems, and continuing to build the community of interest that will lead to widespread availability and adoption of medical device interoperability for the improvement of patient safety and clinical workflow efficiency. Our work has reached a level of federal interest, national recognition, and resource development

that underscores our ability to provide strong clinical leadership in all of these areas.

For Option-Year 2 of this grant, the following set of aims was agreed on with TATRC, including updates to Aims 1, 3, 4, 6, and 9 as specified in the no-cost extension ending September 2015:

Standards Development
- **Aim 1**: Work on development of the following: AAMI/UL2800, which will help with device interoperability certification; the AAMI standard for Integrated Clinical System for PCA (for implementation of PCA safety); and the AAMI Interoperability Working Group, which is developing interoperability standards strategy and overseeing standards development in that domain. **Aim 1 modified** effective April 2015: Continue to work closely with standards committees and standards development organizations to provide subject matter expertise and functional examples of medical device interoperability, and shepherd the transition of F2761-09(13), the "ICE" standard, from ASTM to AAMI. (Dr. Goldman is chair of ASTM Committee F29, where the ICE standard was developed.)
- **Aim 2**: Develop foundational content for a standard for an ICE-compliant clinical Data Logger.
- **Aim 3**: Based on experience with our open ICE platform in our MD PnP Interoperability Lab, provide expertise to other standards development organizations, e.g. IEEE, AAMI, IEEE, UL, ISO, ASTM, HL7, IHE (Integrating the Healthcare Enterprise), and OMG (Object Management Group). **Aim 3 modified** effective April 2015: Provide interoperability demonstrations and education at the AAMI annual meeting and standards meeting in June 2015; based on the feedback received at these meetings, refine our technology and document our findings.

Clinical and Engineering Requirements for Safe Medical Device Interoperability
- **Aim 4**: Create a database of the clinical requirements we have been developing through various projects, and explore ways of making these requirements useful for the broader community. **Aim 4 modified** effective April 2015: Implement workflow to more effectively support standards activities using our research data, and demonstrate these capabilities for feedback at the next AAMI-UL JC2800 meeting in June 2015.
- **Aim 5**: Enhance our requirements gathering process through (1) the evaluation of collaborators' prototype research implementations based on our OpenICE platform and tools, and (2) bringing subject matter experts to our lab as part of a Visiting Scholars program.

Interoperability & Security Requirements for Medical Device Procurement
- **Aim 6**: Identify requirements that are central to meet near-term and long-term needs of DoD and Healthcare Delivery Organizations (HDOs) for medical device procurement, including an adoption pathway roadmap that is reasonably aligned with expectations for industry adoption and that can serve as a basis for procurement strategy. **Aim 6 modified** effective April 2015: For the adoption roadmap, obtain additional input from the members of the IEEE-ISTO ICE Alliance, a non-profit Alliance that was publicly announced in April 2015.
- **Aim 7**: Continue to update MD FIRE procurement language to reflect new information.

Regulatory Science for Safe Medical Device Interoperability
- **Aim 8**: Submit the supplement to the pre-IDE document to the FDA, and provide new relevant information as needed and available.
- **Aim 9**: Once pre-IDE supplement has been submitted, release those documents into the public domain. **Aim 9 modified** effective April 2015: Based on the successful second FDA pre-IDE submission, respond to the FDA's request that we formulate use cases to convey the differences between pair-wise and component-wise interoperability.

Management of External Collaborations

- **Aim 10**: Support and facilitate use of the MD PnP program artifacts and tools (including our Interoperability Lab/Test Bed) for interoperability R&D projects (including mobile applications and Visiting Scholars), "plug-fests", and evolving clinical system integration activities.
- **Aim 11**: Leverage our work to provide leadership and program artifacts and results to related federal initiatives such as the FCC Consumer Advisory Committee and the White House sponsored SmartAmerica NSF Challenge.
- **Aim 12**: Coordinate our work under this award with standards development activities and device-related academic and industry initiatives.

Research Accomplishments

Standards Development, Aim 1: Work to support the development of the following: AAMI/UL2800 (now a family of standards), which will help with device interoperability certification; the AAMI standard for Integrated Clinical System for PCA (for implementation of PCA safety); and the AAMI Working Group on Interoperability, which is developing interoperability standards strategy and overseeing standards development in that domain. **Aim 1 modified** effective April 2015: Continue to work closely with standards committees and standards development organizations to provide subject matter expertise and functional examples of medical device interoperability, and shepherd the transition of F2761-09(13), the "ICE" standard, from ASTM to AAMI as Committee F29 is sunsetted. (Dr. Goldman is chair of ASTM Committee F29, where the ICE standard was developed.)

The MD PnP Program has continued to lead interoperability standards efforts and to work closely with several standards development groups to provide subject matter expertise and functional examples of interoperability: the AAMI/UL Joint Committee (JC) 2800 standard for certification of safe medical device interoperability, the AAMI Interoperability Working Group (IOWG), and the AAMI Task Group on Patient-Controlled Analgesic (PCA) Integrated Clinical System.

In September 2014 we collaborated with DocBox and other members of the AAMI/UL JC2800 standard committee to prepare the first draft of the "Systems Requirements from Clinical User Perspective" document, the "Clinical Requirements" document and the "Hazard Analysis" document. We received feedback from the UL and AAMI committees for these documents and incorporated suggested changes. We worked with DocBox and the AAMI/UL JC2800 standard committee in Q2 to continually engage I detailed analysis of interoperability use cases and system performance and safety considerations.

Members of the MD PnP staff attended the AAMI five-day standards week held in New Orleans, LA, during December 1-5 2014. We presented an overview of our contributions to the AAMI community and attended planning and technical discussion meetings, including the AAMI Task Group on Patient-Controlled Analgesic (PCA) Integrated Clinical System and the AAMI/UL JC2800 standard for certification of safe medical device interoperability. We presented our multi-vendor collaboration using the ICE environment for EBOLA care, a demonstration we had prepared in response to a request from the White House. We also presented our use of the commercial "Serena RM" requirements management tool, which is used internally for MD PnP development work and to host a database of clinical requirements for standards development. The standards committees expressed interest in using our tools to support requirements management for the standards work.

The complex process to transition standards – including F2761-09(13), the "ICE" standard – from ASTM to AAMI, as Committee F29 was sunsetted, delayed progress within both F29 and AAMI. In his role as chair of ASTM Committee F29, Dr. Goldman has been leading the transition of the F29 committee and standards portfolio to AAMI (planned completion by December 2015). Most of the F29 projects were incorporated under a new AAMI standards committee "AAMI AR" (for anesthesia and respiratory), but the ICE standard, including future parts, was moved to the AAMI Interoperability Working Group (IOWG), for which Dr. Goldman serves as co-chair. The IOWG will progress the original ICE standard as well as related work, such as the ICE Data Logger standard. This standards work is closely coordinated with AAMI-UL JC2800 and other related standards development initiatives.

Standards Development, Aim 2: Develop foundational content for a standard for an ICE-compliant clinical Data Logger.

We have tested several strategies to capture and store device data, including defining the optimal data architecture for various clinical scenarios and testing methods to directly intercept device data streams and import the data into MySQL tables that can be displayed on a browser.

We completed the development of foundational content for the draft ICE-Compliant Data Logger standard for submission to a standards development organization, and discussed the adoption plan with ASTM and AAMI. We have also discussed the adoption pathway for this standard with patient care and patient safety organizations such as MITRE, CRICO, and USAMMA. It is anticipated that the ICE Data Logger standard will be developed within the AAMI IOWG once the transition of ASTM F29 to AAMI is completed. The first steps will include obtaining IOWG committee support and drafting a New Work Item Proposal to submit to the AAMI Standards Board to initiate the development of the new standard.

Aim 2 has been completed for purposes of this grant.

Standards Development, Aim 3: Based on experience with our open ICE platform in our MD PnP Interoperability Lab, provide expertise to other standards development organizations, e.g. IEEE, AAMI, IEEE, UL, ISO, ASTM, HL7, IHE (Integrating the Healthcare Enterprise), and OMG (Object Management Group). **Aim 3 modified** effective April 2015: Provide interoperability demonstrations and education at the AAMI annual meeting and standards meeting in June 2015; based on the feedback received at these meetings, refine our technology and document our findings.

Our work on developing standards using OpenICE as a prototype platform for interconnectivity engineering, research, and technology was presented to the AAMI alarms coalition, IEEE-ISTO, UL, ASTM, the FDA cybersecurity guidance council, NIST, AAMI, FCC, UL, and OSTP in a site visit to our Lab.

We continue to provide interoperability demonstrations and test laboratory resources through open house technical workshops, and site visits, as well as education and outreach via the community forum and webinars hosted on our ICE technical site (OpenICE.info).

We provided interoperability demonstrations and education at the AAMI annual meeting and standards meeting in Denver in June 2015. OpenICE was demonstrated by MD PnP engineer Jeff Peterson at an exhibit. An accompanying lecture on the Medical Internet of Things was delivered by Dr. Goldman. The AAMI venue, which our team attends each year, provides important feedback on interoperability, system integration, and adoption from the perspectives of Clinical Engineers and Health Technology Managers. Based on the feedback received at

these meetings, we updated the OpenICE.info web site with tutorial content and have been refining our technology and documenting our findings.

Clinical and Engineering Requirements
While we have transitioned into new requirements-centered aims for the purposes of this award, our early objectives of continued analysis of clinical scenarios to define detailed workflows, clinical requirements, and related engineering requirements, and identifying appropriate use cases for use by others are supported by ongoing work. We continue to identify and refine high-level clinical scenarios, as a foundation for developing technical specifications for medical device interoperability. With TATRC support, we have been able to organize requirements across multiple projects and sources – NIH, FDA, ONC, NSF, etc. – to pull together and vet information that will facilitate adoption by the DoD, the VA, and device manufacturers. We have expanded our work on use cases from the ASTM ICE standard to include ISO, IEC, AAMI, AAMI/UL, and other related standards work.

Clinical and Engineering Requirements for Safe Medical Device Interoperability, Aim 4: Create a database of the clinical requirements we have been developing through various projects, and explore ways of making these requirements useful for the broader community. **Aim 4 modified** effective April 2015: Implement workflow to more effectively support standards activities using our requirements tools, and demonstrate these capabilities for feedback at the next AAMI/UL JC2800 meeting in June 2015.

We have successfully implemented Serena RM, a commercially available requirements management database well suited to support collaboration. We used it to incorporate the requirements we developed under our NIH grant – including generic and ICE-specific requirements, PCA-specific safety and clinical requirements and associated attributes, and collaborator comments on these requirements. We have also used Serena RM to export requirements and comments, and presented them to AAMI/UL JC2800 in the "Systems Requirements from Clinical User Perspective" document. We are using these requirements to establish the scope of the exemplar used for AAMI/UL JC2800, based on our design documentation (requirements and hazard identification).

Within the MD PnP Program, we have refined the project schema and released a production version of our PCA Safety requirements set. We are continuing to refine and elaborate upon the set via weekly requirements reviews with the members of the development team.

At the December 2014 AAMI requirements week, the response to initial sharing of Serena RM requirements output was very positive, and we subsequently received renewed interest from the joint committee in utilizing our tools to aid standards development. In response, we created a demo schema and workflow within Serena RM to more closely align with the standards development work by AAMI/UL JC2800. This enables our MD PnP internal and external standards development work to continue in parallel. We demonstrated this schema and workflow to members of the AAMI/UL JC2800 team at a working session in our Lab prior to their June 2015 meeting, and will continue to refine our project schema for this collaborative AAMI/UL JC2800 standards work.

The implementation of requirements in Serena RM is very powerful because of the capability to export Excel documents and re-import them with tracking of edits to requirements. This enables a pathway of "open sourcing" requirements for use by the extended community of researchers and manufacturers – an exciting enabler of innovation. We tested a workflow based on exporting Serena RM content to Excel format, sharing the Excel document with standards committee members, and importing and tracking committee input using Serena RM's

specialized importation capabilities. While technically effective, we found that this approach may be too resource intensive to maintain as the AAMI/UL specialized working groups proliferate.

We have provided AAMI/UL JC2800 with extensive use case materials and have used our Lab's subject matter expertise to contribute to a wide range of committee documents. In addition, we host six AAMI/UL JC2800 committee working groups on a secure MD PnP-resourced project site (via Basecamp). The site is provided without charge to the committee, and is open to all standards development committee members to enable discussion and sharing.

Clinical and Engineering Requirements for Safe Medical Device Interoperability, Aim 5:
Enhance our requirements gathering process through (1) the evaluation of collaborators' prototype research implementations based on our OpenICE platform and tools, and (2) bringing subject matter experts to our lab as part of a Visiting Scholars program.

In Q1 several graduate students in the Technology Management program at Georgetown University completed their capstone projects in the MD PnP Lab. A second class of graduate students began their capstone projects and conducted research and training activities in the MD PnP Lab during Q3. We are working with the Dean of the School of Continuing Studies and several investigators to develop more OpenICE implementation projects for a long-term collaboration between MD PnP and Georgetown University.

Several research collaborations were established and are ongoing to test prototype implementations of OpenICE in different clinical scenarios at various locations. These projects force specificity into requirements for the communication of interoperable medical device data elements to enable each use case. For example, a team of clinicians and computer science students at the University of Montana worked with our team and OpenICE remotely on a project on the audibility of intraoperative alarm systems. From this collaboration we learned a new clinical scenario with its related requirements and the nuances of the software implementation needed to achieve a successful OpenICE research implementation. An OpenICE ventilator alarm management study led by Maria Cvach, RN, of Johns Hopkins University (JHU) was proposed, and we supported a pre-clinical pilot installation at JHU. Requirements for a comprehensive neuromonitoring suite were explored by MGH neuro-critical care experts. A clinical data collection study for PCA safety at MGH that Dr. Goldman proposed with MGH collaborators has been funded by CRICO.

We continue to receive visiting scholars and subject matter experts in our Lab. During this grant year, these included Dan Hoffman, Chief Innovation Officer for Montgomery County, MD; students of Insup Lee, Professor of Computer Science at University of Pennsylvania; Bill Shaw, Executive Director of the Martinos Center for Biomedical Imaging; Sander Mertens, Solutions Architect at PrismTech; Kristine Kim, medical student at Boston University; technical and strategic leadership teams from Drager USA; and residents and research fellows from the Department of Anesthesia, Critical Care, and Pain Management at MGH.

While these kinds of activities are ongoing, **Aim 5** has been completed for purposes of this grant.

Interoperability & Security Requirements for Medical Device Procurement, Aim 6: Identify requirements that are central to meet near-term and long-term needs of DoD and Healthcare Delivery Organizations (HDOs) for medical device procurement, including an adoption pathway roadmap that is reasonably aligned with expectations for industry adoption and that can serve as a basis for procurement strategy. **Aim 6 modified** effective April 2015: For the adoption

roadmap, obtain additional input from the members of the IEEE-ISTO ICE Alliance, a non-profit Alliance that was publicly announced in April 2015.

We believe that ICE systems will be deployed in a wide variety of settings, with potentially different interoperability and/or security requirements. For example, the MD PnP OpenICE implementation includes a web gateway that enables streaming of device data through a standard web browser on a computer or phone. These various domains have very different needs for security, and at times the requirements are contradictory. For instance, an ICE system in an emergency department needs to allow instant access by anyone in the area during what are called "break the glass" scenarios. This functionality should not be allowed in a mobile or home healthcare setting. As we build our OpenICE implementation, we are tracking these issues and evaluating a variety of security technologies ranging from RFID access control to security testing products.

Recently, there has been a dramatic increase in the community's concerns about medical device cybersecurity, and the need to maintain security to support reliable operation of networked medical devices. An obvious issue is that increased connectivity can lead to increased cybersecurity risk, implying that there must be a trade-off between maintaining security and promoting interoperability. Our program has expressed concern that advancement in interoperability may be subjugated to emerging concerns about cybersecurity, thereby delaying the adoption of much-needed interoperability capabilities. To help define a path forward, we are developing a framework to clarify that effective interoperability can improve cybersecurity by enabling system-level base-lining, forensic data logging (such as through the ICE Data Logger), and monitoring. We have been developing collaborations with several academic, commercial, and governmental security experts, as well as standing up formal medical device cybersecurity capabilities in our MD PnP Lab environment.

Interoperability & Security Requirements for Medical Device Procurement, Aim 7: Continue to update MD FIRE procurement language to reflect new information.

In October 2014, at USAMMA's request (Mr. Dan Kennedy), we provided procurement language on interoperability to be assessed for inclusion in military RFAs. We continue to share and refine MD FIRE procurement language and the adoption thereof, for example, with CRICO, MITRE, and other organizations. In addition, the inclusion of medical device interoperability in the 10-year interoperability adoption roadmap was brought to the attention of the ONC leadership over the course of several meetings beginning in February 2015.

Following the MD PnP Program's 10-year Anniversary Open House in October 2014 (see Aim 10 below), we were approached by key leaders of CRICO, the medical insurance and evidence-based risk management consortium, to consult in the development of the language and roadmap for adoption of security and interoperability into the medical malpractice data collection infrastructure for its associated hospital networks. We expect to continue pursuing this exciting collaborative effort for patient safety.

We continue to identify and collate specific requirements that could be added to MD FIRE, in conjunction with the American Hospital Association.

While these activities are ongoing, **Aim 7** has been completed for purposes of this grant.

Regulatory Science for Safe Medical Device Interoperability, Aim 8: Submit the supplement to the pre-IDE document to the FDA, and provide new relevant information as needed and available.

The multi-institutional Medical Device Interoperability Safety Working Group (MDISWG), which Dr. Goldman co-chairs, submitted the Pre-IDE supplement to FDA in March 2014. MDISWG submitted an important follow-up Pre-IDE submission, which included (1) questions that could not be included in the Pre-IDE submission, (2) follow-up questions based on the final FDA response from the Pre-IDE meeting, and (3) deeper and expanded issues on medical device interoperability, partially based on ICE, partially based on the progress made by AAMI/UL JC 2800 (i.e. use of conformity assessment standards), and partially based on the interoperability aims of this grant.

The FDA response was received in Q2, and the MDISWG has held weekly teleconferences during this period of performance to work on providing additional details to the FDA.

Aim 8 is now complete for purposes of this grant. The regulatory follow-on work is being done under **Aim 9** (below).

As part of our response to a White House Office of Science & Technology Policy request to explore medical-technology solutions for the Ebola epidemic (see **Aim 10** below), we reached out to FDA for their support. Our response focused on (1) remote operation of infusion pumps and ventilators used in a quarantine setting, with the aim of reducing the number of times caregivers need to enter the room, and (2) more effective sensor data acquisition and integration to improve surveillance. Dr. Jeffrey Shuren, director of FDA's Center for Devices and Radiological Health, wrote a letter of support that said in part, "CDRH recognizes the importance of these efforts and is ready and willing to collaborate with you, the clinical community and your industry partners to demonstrate the potential of this technology in serving this particular public health emergency."

This letter was instrumental in bringing together device manufacturers and enabled them to share technologies that they had not previously disclosed publicly out of concern that FDA would not permit remote operation of medical devices. This scenario is an example of the kind of liaison role the MD PnP Program is able to play as a result of our long-term collaboration with federal agencies like the FDA, and trusted relationships with manufacturers.

Regulatory Science for Safe Medical Device Interoperability, Aim 9: Once pre-IDE supplement has been submitted, release those documents into the public domain. **Aim 9 modified** effective April 2015: Based on the successful second FDA pre-IDE submission, respond to the FDA's request that we formulate use cases to better convey the differences between pair-wise and component-wise interoperability.

Since receiving the FDA response on the supplemental pre-IDE submission, we have been working with the pre-IDE project team (MDISWG) in weekly teleconference meetings and with the FDA to release more complete "adoptable" information about the pre-IDE for interoperability. The FDA has requested that we be precise in how the information is framed and released, and in particular that we formulate use cases to better convey the differences between pair-wise and component-wise interoperability. This use case work began in March 2015 and will be ongoing in Option-Year 3. We are committed to disseminating the information in the pre-IDE document via publications and other means. The pre-IDE supplement was posted on the MD PnP web site in May 2014 (http://mdpnp.org/MD_PnP_Program___MDISWG.html).

We have been working with the FDA/CDRH on implementing a Research Collaboration Agreement (RCA) on medical device interoperability. This MGH-FDA Public Private Partnership agreement will facilitate joint projects on interoperability and sharing of regulatory science

results, such as the Pre-IDE research. The five-year RCA is expected to be fully executed prior to the end of this calendar year.

Management of External Collaborations, Aim 10: Support and facilitate use of the MD PnP program artifacts and tools (including our Interoperability Lab/Test Bed) for interoperability R&D projects (including mobile applications and Visiting Scholars), "plug-fests", and evolving clinical system integration activities.

In October 2014, the MD PnP Program hosted an open house to celebrate the 10-year anniversary of the MD PnP Interoperability Program and to demonstrate to the broad community our current progress in standards development and reference implementations thereof. More than 70 individuals representing over 25 academic, industry, and regulatory bodies were in attendance. The technical demonstrations were well-received and several new collaborations were established as a result. We plan to continue our efforts to establish reference implementations of the ICE interoperability standard in various locations and use cases, including MGH, Georgetown University, and Johns Hopkins University.

Also in October 2014, Dr. Goldman was contacted by the White House Office of Science & Technology Policy about upcoming robotics workshops focusing on Ebola patient care. He was asked to rapidly identify relevant medical technology-based solutions to the Ebola threat. Over a 20-day period in October-November, the MD PnP Program convened via teleconference a group from government, academia, and industry to prototype innovative approaches to improve patient care and reduce the risk of healthcare workers' exposure to Ebola. Using our Medical Device Interoperability Lab & Test Bed and the OpenICE platform for medical device and data integration, the participants rapidly prototyped technology solutions during a three-day November hackathon focused on two use cases:

- Quarantine: Sensor integration and data acquisition to improve Ebola screening, monitoring, and diagnosis in quarantine
- Hospital: Remote control, closed loop control, and remote data access to improve patient care and reduce the exposure of hospital personnel by limiting the number of times caregivers enter the patient environment to change ventilator and infusion pump settings

In addition to the letter officially expressing their support (see **Aim 8** above), FDA/CDRH sent a representative to the hackathon to meet with collaborators, observe the demonstrations, and answer questions. The hackathon drew a considerable amount of press; links to articles and video about the work can be found at http://mdpnp.org/ebola.html. This work demonstrated how our team was able to respond quickly to the challenges of a national medical threat by providing leadership, convening, and interoperability resources such as subject matter expertise, a neutral technical convening environment, and OpenICE tooling.

Dr. Goldman discussed our work on interoperability solutions for Ebola safety and implications for healthcare transformation at a White House briefing in December. Dr. Goldman also presented the Ebola response project at the Global Cities Summit at NIST in Rockville, MD, in February 2015. This important work will continue in the coming year under the SmartAmerica Global City Teams Challenge (GCTC) banner.

"SmartAmerica Round 2: Global City Teams Challenge" Expo was convened by Presidential Innovation Fellows in June 2015 in Washington DC. Dr. Goldman and Betty Levine (TATRC) presented a use case on "Remotely Caring for Our Most Vulnerable Citizens In-Place during a Pandemic." This use case was formulated at the NIST GCTC kickoff meeting in September

2014, and featured automated detection, triage, and treatment of severe contagious disease outbreaks, with a focus on enabling remote support of local treatment. The Ebola-focused application became the central application of the more general GCTC use case as a result of the Ebola epidemic and the White House request in October 2014. At the GCTC Expo in DC, our extended team of collaborators demonstrated the Ebola responses from the hackathon, which led to some ongoing work with the vendors that were involved.

In January 2015 Dr. Goldman met with senior leadership of Kaiser Permanente to discuss adoption of the Integrated Clinical Environment (ICE) concepts. Topics of discussion included ICE reference implementations, clinical and system requirements, feedback to SDOs to help standards conform to ICE requirements, a forum to express clinical needs for ICE implementations, and test tools.

In February MD PnP Lead Engineer Dave Arney gave presentations and panels on safety, security, scalability, and other considerations for medical device interoperability at the NIST CPS TestBed workshop. Representatives from the MITRE Corporation visited the MD PnP Interoperability Lab to discuss a potential FDA medical device cybersecurity project in collaboration with MD PnP. Dr. Goldman and the MD PnP technical team led discussions related to the needs of the healthcare security space and the capabilities of ICE-compliant technologies to meet this need.

Management of External Collaborations, Aim 11: Leverage our work to provide leadership and program artifacts and results to related federal initiatives such as the FCC Consumer Advisory Committee and the White House sponsored SmartAmerica NSF Challenge.

Dr. Goldman spoke at the February 19-20 2015 Medical Devices Summit in Boston, MA, about "Achieving Interoperability in Medical Device Technology to Support Innovation." He addressed interoperability barriers and solutions, considerations for the medical internet of things to improve patient care, integration vs. interoperability, and the relationship between security and interoperability.

As we have in past years, the MD PnP Program provided demonstrations of our work at the annual HIMSS conference (Healthcare Information Management & Systems Society) held in Chicago, IL, on April 13-16, 2015. Our demonstration (Automated Validation of Medical Device Data for EMRs) was part of the Office of the National Coordinator for Health Information Technology (ONC) section of the Interoperability Showcase. The demonstration (shown in Figure 1 below) included an OpenICE installation with a GE Dash patient monitor and an ICE Supervisor running several apps, as well as a DocBox ICE Implementation running a charting app. The OpenICE Validation App, running on the OpenICE Supervisor, was the focus of the demonstration.

Patient data from medical devices like patient monitors must be validated before it is stored in electronic health record (EHR) systems. Currently, validation is a manual process, and is performed intermittently for a few vital signs. As more devices are connected, and as device interfaces begin to support communication of more information, many more vital signs will be able to be recorded. To address this problem, we created an automatic validation app that acquires the patient's vital signs and compares multiple sources to determine whether to categorize the data as either "preliminary" (i.e. the vital sign data does not appear to be correct) or "final," based on a user-specified standard deviation. We implemented connectivity to an EHR as an HL7 FHIR gateway from OpenICE. The monitor we used can measure heart rate from EKG, from the pulse oximeter, or from an invasive blood pressure line. If those sources all reported exactly the same heart rate, then the app would categorize them as "final." The vital

sign data with the automated assessment was transmitted to an ICE-system-based charting application (developed by DocBox, Inc.) for display.

Fig 1. MD PnP Demonstration at HIMSS 2015 Conference
Background screen shows real-time analysis, vital sign monitor is connected to a physical vital signs simulator (not shown), OpenICE charting application is shown on tablet, and DocBox application is shown at bottom right receiving and charting data from the validation app

Management of External Collaborations, Aim 12:
Coordinate our work under this award with standards development activities and device-related academic and industry initiatives.

This past year we founded an interoperability standards consortium – the ICE Alliance – which was announced to a limited audience at the HIMSS 2015 conference in April. We are working with the IEEE-ISTO (Industry Standards & Technology Organization) to establish a membership structure. The ICE Alliance comprises a growing number of companies, hospitals, academic institutions, expertise advisors, and NGOs to work together toward further developing vendor-neutral technological solutions for healthcare threats. We have founding support from the STA, Partners Healthcare, Intel, and DocBox, Inc., among others, as well as the full support of the FDA, FCC, and other federal agencies to provide a rapid regulatory pathway for adoption of our collaborators' medical device interoperability solutions. We are still in the early phase of formation of the alliance, and will need committed funding to ensure stability.

The coordination of our MD PnP program work with industry initiatives like IEEE-ISTO is facilitated by our leadership and participation in standards efforts like AAMI/UL JC2800 (see **Aim 1** above), as many manufacturers are involved in standards activities.

Key Research Accomplishments

- **Standards work related to medical device interoperability.** We have leveraged our foundational work on the ICE standard (ASTM F2761) to bring those concepts into other related standards work. We have been actively involved in the AAMI/UL JC2800 standard for certifiable safety of medical device interfaces, and the new AAMI standards task groups on PCA safety. We have drawn on requirements and architecture material from our TATRC and NIH work to assist the efforts of these groups, which provide a forum for sharing lessons learned from our projects relative to the gaps in existing standards and recommendations on how they can be improved. A key achievement this year was the drafting of substantial content for a new ICE Data Logger standard, which will be completed and submitted to AAMI as a New Work Item Proposal during Option-Year 3.

- **Interoperability procurement language.** Our MD FIRE (Medical Device Free Interoperability Requirements for the Enterprise) sample procurement language has been shared with many organizations, and we worked with Dan Kennedy at USAMMA to deliver procurement language on interoperability to be included in military RFAs. The most recent version of MD FIRE is available on the MD PnP website (http://mdpnp.org/mdfire.php). The MD FIRE document text is being re-assessed by several organizations to add new requirements, especially related to cybersecurity.

- **Clinical and Engineering Requirements for Safe Medical Device Interoperability.** Our Serena RM requirements management database has enabled us to collect generic ICE requirements and PCA Safety clinical requirements and associated attributes, along with collaborator comments. Using Serena RM, we have presented requirements to AAMI/UL JC2800 to establish the scope of the exemplar used for AAMI/UL JC2800, based on our design documentation (requirements and hazard identification), and Serena RM has attracted considerable interest in the standards community as a facilitating tool for standards development based on requirements. MD PnP is thus able to open a pathway of "open sourcing" requirements for use by the extended community of researchers and manufacturers – an exciting enabler of innovation.

- **Regulatory Science for Safe Medical Device Interoperability.** The MD PnP program has from its inception worked closely with the U.S. FDA to identify a regulatory pathway that will support the MD PnP concept of platform-based interoperability – one which will not require re-validation or re-clearance of an entire networked system as each new independently validated device is added to the medical network. Following the January 2010 three-day workshop on medical device interoperability (http://mdpnp.org/FDA_Workshop.html), which was planned by the MD PnP program in conjunction with the Continua Health Alliance and the FDA and held at the FDA, a working group comprised of companies, standards organizations, clinical and legal participants, and the FDA met weekly to work on the development of a prototype regulatory submission of an interoperable medical device system. The Medical Device Interoperability Safety Working Group (MDISWG) completed and submitted to FDA a pre-IDE document, followed by a supplement based on FDA response, in 2012-13. An additional supplement was submitted in 2014 and is publicly available on the MD PnP program's web site (http://mdpnp.org/MD_PnP_Program___MDISWG.html). This work

has advanced regulatory science, thereby facilitating industry regulatory submissions related to interoperable systems.

- **MD PnP Lab at Massachusetts General Hospital**. The MD PnP Interoperability Lab opened in May 2006 to provide a vendor-neutral "sandbox" to evaluate the ability of candidate interoperability solutions to solve clinical problems, to model clinical use cases (in a simulation environment), to develop and test related network safety and security systems, and to support interoperability and standards conformance testing. The Lab has been used by MD PnP and our collaborators in academia and industry, as well as government, to further develop demonstrations of interoperability-based patient safety improvements, and has served as a test bed for clinical and industry testing. We hold regular open house demonstrations to share our work with interested parties. The lab has hosted inter-institutional "hackathons" for groups such as the SmartAmerica Closed-Loop Healthcare Group, and visiting scholars from various institutions. The benefit of a fully functional independent lab testbed was exemplified by the ability to rapidly respond to medical technology research needs to address the Ebola epidemic.

- **Relationships with other federal agencies.** We have continued to work collaboratively with NIST, the FDA, NSF, the Office of the National Coordinator for Health IT, and the Office of Science & Technology Policy (OSTP) at the White House.

The MD PnP Program has been functioning as a *de facto* national center for interoperability in terms of the resources – including our Lab and subject matter expertise – that we are able to make available to the broader research community and to industry. TATRC/ USAMRMC research support has been a key enabler of these capabilities.

Reportable Outcomes

Quarter 1, September 21, 2014 – December 20, 2014:

- October 2014 – December 2014 – Two-to-four teleconference calls /month of the AAMI/UL JC2800 standards committee
- October 2014 – December 2014 – Weekly teleconference calls of the Medical Device Interoperability Safety Working Group (MDISWG) to advance the FDA Pre-IDE submission supplement
- September 29-30 2014 – Smart America Round 2: Global City Teams Challenge at NIST Washington, DC
- October 10 2014 – Meeting of the UDI Workgroup, Brookings Institute, Washington, DC
- October 21 2014 – FDA Workshop on Collaborative Approaches for Medical Device and Healthcare Cybersecurity, Washington, DC
- October 21 – November 6 2014 – 12 teleconferences to plan for collaboration on Open Medical Device and Data Integration Platforms to support the management of Ebola and November 7 Ebola Workshop
- November 4-6 2014 – three-day hackathon at MD PnP Lab to create Ebola demonstrations
- December 1-5 2014 – AAMI Standards Week, New Orleans, LA.

Quarter 2, December 21, 2014 – March 20, 2015:

- January 2015 – March 2015 – Two-to-four teleconference calls/month of the AAMI/UL JC2800 standards committee
- January 2015 – March 2015 – Weekly teleconference calls of the Medical Device Interoperability Safety Working Group (MDISWG)

- February 17 2015 – Draeger Leadership visit to MD PnP Lab to discuss industry adoption of interoperability
- February 19-20 2015 – Medical Devices Summit in Boston, MA
- February 24-25 2015 – NIST Wireless TestBed workshop in Washington, DC
- February 26 2015 – MITRE visit to MD PnP Lab to discuss interoperability and cybersecurity

Quarter 3, March 21, 2015 – June 20, 2015:

- April 2015 – June 2015 – Two-to-four teleconference calls /month of the AAMI/UL JC2800 standards committee
- April 2015 – June 2015 – Weekly teleconference calls of the Medical Device Interoperability Safety Working Group (MDISWG)
- March 24-28 2015 – Industrial Internet Consortium (IIC) meeting in Chicago, IL – initial activities to stand up the Healthcare Task Group vertical in IIC, and presentation to Object Management Group (standards development organization)
- March 29 2015 – AAMI-UL 2800 WG03 TG for General Requirements (local in-person meeting)
- April 2 2015 – INCOSE Healthcare Working Group Webinar
- April 2 2015 – FDA Public Workshop: An Interactive Discussion on the Clinical Considerations of Risk in the Post-Market Environment (role of more complete medical device information in post-market surveillance)
- April 13-16 2015 – HIMSS 2015 in Chicago – demonstrated OpenICE "Auto Validation" app (https://www.openice.info/docs/3_apps.html#auto-validate)
- April 16 2015 – UL Health Sciences Council in Chicago (discussion on standards for interoperability)
- April 28 2015 – Doug Fridsma (AMIA President) MD PnP Lab demonstration
- June 5-8 2015 – AAMI annual conference in Denver, CO

Quarter 4, June 21, 2015 – September 20, 2015:

- July 2015 – September 2015 – Two-to-four teleconference calls /month of the AAMI/UL JC2800 standards committee
- July 2015 – September 2015 – Weekly teleconference calls of the Medical Device Interoperability Safety Working Group (MDISWG)
- July 21 2015 – AAMI/AR & US TAG to ISO/TC121 annual standards meetings
- July 23 2015 – NIST visit to MD PnP Lab
- August 10 2015 – AAMI UL JC2800 WG03 TG01 Webconference in Boston
- August 12 2015 – Device Integration Platform (ICE Platform) in Ft Lauderdale, FL
- August 31 2015 – MD PnP Lab Visit by Tim Rudolf (US Air Force)
- September 2 2015 – Interoperability strategy, laboratory testing, CRADA discussion, USAMMA, Ft. Detrick, MD
- September 3 2015 – White House Precision Medicine Initiative – discussion of device interoperability, Washington, DC

Presentations on Medical Device Interoperability Topics:

Dr. Goldman delivered invited presentations on topics related to medical device interoperability for improving patient safety and healthcare efficiency to the following groups during the past year:

Quarter 1, September 21, 2014 – December 20, 2014:

- "MD PnP Program Updates" at University of Pennsylvania PRECISE Center, October 9 2014, Philadelphia, PA
- Updates on MD PnP research to several committees at ASA Annual Meeting, October 11-14 2014, New Orleans, LA
- "Medical Device Interoperability," Congressional Staff Briefing, October 20 2014, Washington, DC
- MD PnP Research Demonstrations at Lab Open House, October 22 2014, Cambridge MA
- "Open Medical Device and Data Integration Platforms to support the management of Ebola," presentations to press and lab visitors, November 6 2014, Cambridge MA
- "A Systems Oriented Approach to Optimize the Performance of Clinical Alarms," keynote address at Clinical Alarms Safety Symposium, November 20 2014, Washington, DC
- Grand Rounds at San Diego Naval Hospital, November 21 2014, San Diego, CA
- "Technology Advancements in the Intelligent Medical Home: From the Leaders Perspective," keynote and panel at mHealth Symposium, December 6-7 2014, Washington DC
- "Open Medical Device and Data Integration Platforms to support the management of Ebola," White House briefing, December 8 2014, Washington, DC
- "Overview of MGH MD PnP Program," lecture at Georgetown University MD PnP Visiting Scholars presentations, December 16 2014, Cambridge, MA

Quarter 2, December 21, 2014 – March 20, 2015:

- "Innovations in Standards for Interoperability," January 8 2015, Phoenix, AZ
- Demo of Web-based interoperability requirements research tool at MD PnP Lab, January 21 2015, Boston, MA
- " Medical Device and Data Integration Platforms to Support the Management of Ebola," February 2015, Rockville, MD
- "Achieving Interoperability in Medical Device Technology to Support Innovation," February 2015, Boston, MA
- Boston Wireless Session: Discuss Content and Flow for topic of "Interoperability," February 2015, Boston, MA
- Panel at Agency for Healthcare Research and Quality (AHRQ) Headquarters, February 24-25 2015, Rockville, MD
- "Overview of MGH MD PnP Program," lectures for Boston University, Bentley University, and Georgetown University graduate students, MD PnP Visiting Scholars presentations, February – March 2015, Cambridge, MA
- "Medical Device Interoperability Roadmap" lecture at Interoperability Advisory Group meeting, March 17 2015, Washington DC

Quarter 3, March 21, 2015 – June 20, 2015:

- Keynote and panel at Object Management Group Conference March 25 2015, Washington DC
- "Open Sourced Technology Advancements in Medical IIC," invited lecture at Industrial Internet Consortium meeting, March 25 2015, Washington DC

Quarter 4, June 21, 2015 – September 20, 2015:

- ***China Health Information Technology Exchange Conference*** *(August 3-9 2015):* "Practice and Progress in Achieving the Interoperability of Health IT and Medical Devices" (information sharing to global audience, not funded by this grant)
- ***Smart Monitoring Conference*** *(Fort Lauderdale, FL, August 15-16 2015):* Participated in FDA panel and presented "Ebola Care Medical-Technology Response: Open Medical Device & Data Integration Platforms to Support Management of Ebola Virus Disease"
- ***MHSRS- Military Health System Research Symposium*** *(Fort Lauderdale, FL, August 17-20 2015):* Training & Informatics session (MHSRS-15-1192) "Autovalidation of Medical Device Data for EHRs Using Apps on an Open Medical Device Integration Platform (ICE Platform)," August 19 2015
- ***Internet of Things Solutions World Congress, Barcelona*** *(Sept 16-18 2015):* "Remote Caring for Vulnerable Population during a pandemic: Demonstrating the Vision of the Medical Internet of Things"

Engineers from the MD PnP research team delivered the following presentations on medical device interoperability topics during the past year:

- Peterson J, "Open Sourced Interoperability," lecture at Northeastern Healthcare Technology Symposium, November 5-6 2014, Groton, CT
- Peterson J, "Open Source Interoperability: A Technical Review of OpenICE and DDS," lecture at Georgetown University MD PnP Visiting Scholars presentations, December 16 2014, Cambridge, MA
- Peterson JT, "Open Source Interoperability - Intro to OpenICE," Educational Webinar session #6 - Innovators Showcase: Three Clinical Engineers Leading the Way, February 12 2015, Cambridge, MA
- Arney DE, "Healthcare IoT: The Impact in the Hospital," MIT Connected Things Forum, February 26 2015, Cambridge, MA

Web Site:

- www.mdpnp.org is maintained as a major communication vehicle for the program and all major programmatic initiatives, including MD FIRE contracting language, publications, posters, links to streaming video of talks from plenary meetings and from the FDA Workshop, and downloads of sharable documents and code.

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Conclusions

The implementation and analysis work performed by our team and with collaborators in our MD PnP Interoperability Lab, coupled with the FDA Pre-IDE submission, standards development work, MD FIRE updates, and OpenICE software development, is helping to define an adoption roadmap that considers the state of legacy technology, market influences, emerging technology capabilities, and standards convergence.

As with prior TATRC BAA support, this BAA has provided core program support that enables the Medical Device "Plug-and-Play" (MD PnP) Interoperability Program to provide important clinically focused leadership of the growing move towards open standards and related technologies for networking medical devices to support clinical solutions for improving patient safety and healthcare efficiency. The majority of this BAA has been used for core personnel salary support, which provides the foundation to identify and access other available resources, to lead relevant standards work, and to build collaborations to achieve device interoperability objectives. These collaborations include activities and relationships with federal agencies and the White House; clinical, engineering, and IT societies; clinicians in the US, Canada, Europe, and Japan; and integrated healthcare delivery organizations like Kaiser Permanente, Johns Hopkins, Partners HealthCare, and the Veterans Health Administration.

Although we have been successful in past years in attracting funding from several federal agencies (NIH, NSF, NIST), as well as CIMIT, all of this funding is project-specific and does not

support the standards development work, active information sharing, convening, and program infrastructure that the TATRC funding has so greatly enhanced.

Notable achievements with national and sometimes international impact that were enabled or facilitated by this TATRC support include:
- We led the development of an international standard for the Integrated Clinical Environment (ICE) and saw it through to adoption and publication by ASTM International; we subsequently prepared a new draft standard on the ICE Data Logger, to be completed and submitted to AAMI as a new work item; the ICE standard has become the basis for many other forward-looking standards being written or revised in ISO, IEC, AAMI, and UL;
- Four major healthcare delivery systems collaborated under MD PnP program leadership on shared language for procurement of interoperable medical devices, and this language (MD FIRE) is being reviewed for potential adoption by many other organizations, including USAMMA;
- Fourteen medical societies (including the AMA) have endorsed the need for medical device interoperability;
- Strong collaborations have been established with the VA and with federal agencies, including the Office of the National Coordinator for Health IT and the White House, reinforcing the importance of medical device interoperability for the national healthcare agenda;
- The FDA held a jointly sponsored Workshop on Medical Device Interoperability, worked with an MD PnP/industry working group on defining components of a prototype regulatory submission of a system of integrated medical devices, and has accepted the pre-IDE submission and subsequent supplement produced by that working group, which will continue to inform regulatory science, thereby de-risking FDA regulatory clearance of innovative interoperable medical technologies.

These activities are highly interdependent and synergistic, and TATRC/USAMRMC support has been instrumental in providing the "program glue" to effectively leverage these synergies to realize our mutual program objectives.

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Other relevant documents are linked to from the text of the report.